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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/631,609 08/04/00 TANAAMI

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EXAMINER

HM22/0910

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ART UNIT

PAPER NUMBER

1655

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DATE MAILED:

09/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/631,609

Applicant(s)

TANAAMI, TAKEO

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicant's election with traverse of Group III, claims 11-30, filed 4 August 2001 in Paper No. 3 is acknowledged. Traversal is on the grounds that the claims of Groups II and III recite the same invention and differ only in the breadth and language used. Additionally, Applicant argues that the invention of Group I recite further treatments as may be done by the inventions of Groups II and III. These arguments are not found persuasive because, the inventions of Groups I, II and III are independent and distinct i.e. they are not capable of use together, they have different functions and different modes of operation. Specifically, the invention of Group I functions to provide a biochip for nucleic acid synthesis and operates by providing amplifying and transcribing means; the invention of Group II functions to provide biochips comprising DNAs, RNAs or proteins and operates by applying positive and negative voltages to an electrode on a side of said substrate; and the invention of Group III functions to provide biochips of amplified DNA and operates by depositing biomolecules on the chip using a capillary array and wherein the biomolecules are DNA which are amplified within said capillaries. Because the inventions are independent and distinct for the reasons stated above, the Restriction Requirement is still deemed proper and therefore is made FINAL.

Claims 1-10 are withdrawn from further consideration.

Claims 11-30 are discussed below.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 11-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 11-15 are indefinite in Claim 11, lines 2-3 for the recitation "said biomolecules are deposited onto the substrate" because "deposited" lacks proper antecedent basis in the "arranging biomolecules" recited in line 1. It is suggested that Claim 11 be amended to provide proper antecedent basis e.g. replace "deposited" with "arranged" or replace "arranging" with "depositing".

b. Claims 11-15 are indefinite in Claim 11, line 5, for the recitation "sites on said substrate" because "sites" lacks proper antecedent basis in the claim. It is suggested that Claim 11 be amended to provide proper antecedent basis e.g. in line 3, after "onto" insert "a site on".

c. Claims 14 and 15 are indefinite in Claim 14, line 1 for the recitation "DNA contained with said capillary array" because "DNA" lacks proper antecedent basis in Claim 11 which recites "biomolecules". The further lacks antecedent basis in Claim 11 because biomolecules of Claim 11 are not "contained within the capillaries". It is suggested that Claim 14 be amended to provide proper antecedent basis e.g. replace "DNA" with "said biomolecules are" and in line 2, after "capillary array" insert to insert and "wherein said biomolecules are DNA which".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 11-13, 16, 18, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Balch (U.S. Patent No. 6,083,763, issued 4 July 2000).

Regarding Claim 11, Balch discloses a method for producing biochip by arranging biomolecules in arrays on a substrate, wherein said biomolecules are deposited onto the substrate using a capillary array comprising a plurality of capillaries arranged at the same spacing interval as that of sites on said substrate (Column 12, lines 13-29 and Claim 1).

Regarding Claim 12, Balch discloses the method wherein said biomolecules are deposited by applying voltage across said capillary array and said substrate i.e. via electro-osmotic or electrophoretic force (Column 15, lines 44-52 and Claims 18-19)

Regarding Claim 13, Balch discloses the method wherein said biomolecules are deposited by pressurizing each capillary of said capillary array (Column 15, lines 44-52 and Claim 16).

Regarding Claim 16, Balch discloses an apparatus for producing biochips comprising: capillary holder means for supporting a plurality of capillaries arranged at a same spacing interval as that of sites on a biochip (i.e. capillary sleeve/array template, Column 12, lines 63-67); means for adjusting a gap formed between said capillary holder means and said substrate i.e. print head and positioning device (Column 15, lines 26-37 and Claim 7); and means for transferring biomolecules from said capillaries to said substrate e.g. electro-osmotic or electrophoretic force (Column 15, lines 44-52 and Claims 15, 18 and 19).

Regarding Claim 18, Balch discloses said means for transferring comprises means for pressurizing said capillaries to deposit biomolecules onto said substrate (Column 15, lines 44-60, Claims 15 and 16 and Fig. 1).

Regarding Claim 25, Balch disclose the apparatus of Claim 16 comprises means for positioning said substrate above or below said capillaries i.e. print head and positioning device (Column 15, lines 26-37 and Claim 7).

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Regarding Claim 27, Balch discloses the apparatus of Claim 18 comprises means for positioning said substrate above or below said capillaries i.e. print head and positioning device (Column 15, lines 26-37 and Claim 7).

6. Claims 11, 13-16, 18, 19, 21, 22, 24, 25, 27, 28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Haff et al. (U.S. Patent No. 5,720,923, issued 24 February 1998). The claims are drawn to an apparatus for producing a biochip. However, the courts have stated that a preamble is generally not accorded any patentable weight where it merely recites the intended use, and where the body of the claim does not depend on the preamble for completeness but, instead, the structural limitations are able to stand alone (see *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ at 481). In the instant case, the preamble is not accorded any patentable weight because it merely recites the intended use for the method and apparatus i.e. for producing biochips and because the method steps and components of the apparatus are able to stand alone and are capable of performing the intended use i.e. the method steps of arranging biomolecules on a substrate are capable of producing a biochip; and apparatus components comprising a capillary holder means, means for adjusting a gap between the holder and a substrate, and means for transferring biomolecules from capillaries to the substrate are capable of producing a biochip.

Regarding Claim 11, Haff et al. disclose a method comprising the steps of arranging biomolecules in arrays on a substrate wherein said biomolecules are deposited using a capillary array comprising a plurality of capillaries arranged at the same spacing on the substrate (Column 4, lines 18-35).

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Regarding Claim 13, Haff et al. disclose the method wherein said biomolecules are deposited by pressurizing each capillary of said capillary array (Column 19, line 66-Column 20, line 8).

Regarding Claim 14, Haff et al. disclose the method wherein DNA contained within said capillary array is amplified within said capillaries by polymerase chain reaction (PCR) (Column 4, lines 25-31).

Regarding Claim 15, Haff et al. disclose the method wherein the PCR is performed by atmospheric temperature change i.e. heat exchanger blocks (Column 18, lines 35-55).

Regarding Claim 16, Haff et al. disclose an apparatus for producing an array of biomolecules comprising a holder means for supporting a plurality of capillaries arranged in the same spacing interval as that of sites on the array (i.e. clamp bar, Fig. 20 # 234); means for adjusting a gap formed between said capillary holder and substrate (i.e. tube lift assembly, Fig 20, # 236); and means for transferring biomolecules from said capillaries to said substrate (i.e. plungers, Fig. 20 #266).

Regarding Claim 18, Haff et al. disclose the apparatus wherein said means for transferring comprises means for pressurizing said capillaries so that biomolecules contained in said capillaries are deposited onto said substrate i.e. plungers (Column 19, line 66-Column 20, line 8 and Fig. 20 #266).

Regarding Claim 19, Haff et al. disclose the apparatus of Claim 16 further comprising means for amplifying DNA in said capillaries by PCR i.e. heat exchangers (Column 18, lines 34-55).

Regarding Claim 21, Haff et al. disclose the apparatus of Claim 18 further comprising means for amplifying DNA in said capillaries by PCR i.e. heat exchangers (Column 18, lines 34-55).

Regarding Claim 22, Haff et al. disclose the apparatus of Claim 19 wherein said means for amplifying comprises means for PCR by temperature processing (Column 18, lines 34-55).

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Regarding Claim 24, Haff et al. disclose the apparatus of Claim 21 wherein said means for amplifying comprises means for PCR by temperature processing (Column 18, lines 34-55).

Regarding Claim 25, Haff et al. disclose the apparatus of Claim 16 comprising means for positioning said substrate below said capillaries (Column 19, lines 13-25).

Regarding Claim 27, Haff et al. disclose the apparatus of Claim 18 comprising means for positioning said substrate below said capillaries (Column 19, lines 13-25).

Regarding Claim 28, Haff et al. disclose the apparatus of Claim 19 comprising means for positioning said substrate below said capillaries (Column 19, lines 13-25).

Regarding Claim 30, Haff et al. disclose the apparatus of Claim 21 comprising means for positioning said substrate below said capillaries (Column 19, lines 13-25).

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 17 and 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Balch (U.S. Patent No. 6,083,763, issued 4 July 2000).

Regarding Claim 17, Balch teaches the apparatus wherein said means for transferring comprises electro-osmotic or electrophoretic force (Column 15, lines 44-54). The preceding rejection is based on judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Balch is silent with regard to the apparatus comprising a voltage source means. However, the voltage source means recited in Claim 17 is deemed to be inherent in the electro-osmotic or

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electrophoretic force in Balch because electro-osmotic and electrophoretic force requires a voltage source means. Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the apparatus of Balch which transfers biomolecules using electro-osmotic or electrophoretic force by including a voltage source means required for electro-osmotic and electrophoretic deposit to thereby provide all means within the apparatus for performing all functions of their apparatus for the obvious benefits of totally integrated apparatus i.e. rapid, accurate and cost-effective systems (Balch, Column 4, lines 1-6). The burden is on applicant to show that the claimed voltage source means is either different or non-obvious over that of Balch.

Regarding Claim 26, Balch teaches the apparatus comprises means for positioning said substrate above or below said capillaries i.e. print head and positioning device (Column 15, lines 26-37 and Claim 7).

Claim Rejections - 35 USC § 103

9. Claims 14, 15, 19-24 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch U.S. Patent No. 6,083,763, issued 4 July 2000) in view of Haff et al. (U.S. Patent No. 5,720,923, issued 24 February 1998).

10. Regarding Claims 14 and 15, Balch teaches a method for producing biochip by arranging biomolecules in arrays on a substrate, wherein said biomolecules are deposited onto the substrate using a capillary array comprising a plurality of capillaries arranged at the same spacing interval as that of sites on said substrate (Column 12, lines 13-29 and Claim 1) and Balch teach the method wherein PCR product is deposited onto the substrate (Column 35, lines 12-19 and Fig. 14) but they do not teach DNA contained within said capillary array is amplified within said capillaries by polymerase chain reaction. Haff et al. teach a similar method for producing an array of biomolecules wherein the biomolecules are deposited using a

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capillary array comprising a plurality of capillaries arranged in the same spacing interval as that of sites on the array and wherein the DNA within the capillary array is amplified within said capillaries by polymerase chain reaction (Column 4, lines 19-35 and Fig. 20) wherein the capillaries pass through "heat exchangers" to provide the required atmospheric temperature changes for the polymerase chain reaction (Column 18, lines 34-44 and Fig. 20 #212 and #213). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the PCR amplification of the DNA in the method of Balch by amplifying the DNA within the capillaries (Claim 14) by changing atmospheric temperature surrounding each capillary (Claim 15) to thereby very rapidly change the temperature of the capillary and PCR reaction within the capillary to greatly reduce the time required for the PCR reaction as taught by Haff et al. (Column 5, lines 27-33) for the obvious benefits of economy time and labor.

Regarding Claims 19-21, Balch teaches the apparatus of Claims 16-18 for producing biochips comprising: capillary holder means for supporting a plurality of capillaries arranged at a same spacing interval as that of sites on a biochip (i.e. capillary sleeve/array template, Column 12, lines 63-67); means for adjusting a gap formed between said capillary holder means and said substrate i.e. print head and positioning device (Column 15, lines 26-37 and Claim 7); and means for transferring biomolecules from said capillaries to said substrate e.g. electro-osmotic or electrophoretic force (Column 15, lines 44-52 and Claims 15, 18 and 19). Balch teach a PCR product is deposited onto the substrate (Column 35, lines 12-19 and Fig. 14) but they do not teach the apparatus comprises mean for amplifying DNA in said capillaries by polymerase chain reaction. Haff et al. teach a similar apparatus for producing an array of biomolecules comprising a holder means for supporting a plurality of capillaries arranged in the same spacing interval as that of sites on the array (i.e. clamp bar, Fig. 20 # 234); means for adjusting a gap formed between said capillary holder and substrate (i.e. tube lift assembly, Fig 20, # 236); and means for transferring biomolecules from said capillaries to said substrate (i.e.

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plungers, Fig. 20 #266) and further comprising means for amplifying DNA in said capillaries by PCR (Column 4, lines 19-35 and Fig. 20) wherein the capillary PCR simplifies the PCR reaction by reducing thermal gradient problems and shortens the PCR reaction time by providing for very rapid temperature changes (Column 5, lines 11-16 and 28-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the apparatus comprising capillary sleeve/array template through which the capillaries are spatially arrayed and controlled in the method of Balch (Column 12, lines 63-67) by incorporating a heat exchanging capillary sleeve/array template as taught by Haff et al. which also arrays and controls the capillaries but additionally provides the environment for amplifying DNA in the capillary by PCR to thereby provide and deposit PCR products rapidly and accurately as taught by Haff et al. (Column 5, lines 7-35).

Regarding Claims 22-24, Balch teaches the apparatus of Claims 16-18 (Fig. 4) and Balch teaches a PCR product is deposited onto the substrate (Column 35, lines 12-19 and Fig. 14) but they do not teach the apparatus comprises mean for amplifying DNA in said capillaries by polymerase chain reaction by temperature processing. Haff et al. teach a similar apparatus further comprising means for amplifying DNA in said capillaries by PCR by temperature processing (Column 4, lines 19-35 and Fig. 20) wherein the capillary PCR simplifies the PCR reaction by reducing thermal gradient problems and shortens the PCR reaction time by providing for very rapid temperature changes (Column 5, lines 11-16 and 28-33). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the apparatus comprising capillary sleeve/array template through which the capillaries are spatially arrayed and controlled in the method of Balch (Column 12, lines 63-67) by incorporating a heat exchanging capillary sleeve/array template as taught by Haff et al. which also arrays and controls the capillaries but additionally provides the environment for amplifying DNA in the capillary by PCR using temperature processing to thereby provide and deposit PCR products rapidly and accurately as taught by Haff et al. (Column 5, lines 7-35).

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Regarding Claims 28-30, Balch teaches the apparatus of Claims 16-18 comprises means for positioning said substrate above or below said capillaries i.e. print head and positioning device (Column 15, lines 26-37 and Claim 7).


Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:45 TO 4:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
September 7, 2001


W. Gary Jones
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9/7/01